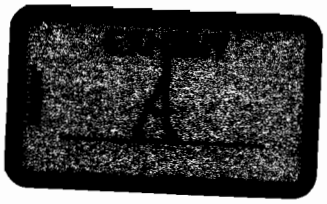
IN THE CIRCUIT COURT
OF
DESOTO COUNTY, MISSISSIPPI

DIANE TRUDDLE; KAYLYN TRUDDLE; RICKY CARMICHAEL; and RICKY CARMICHAEL, JR., INDIVIDUALLY AND AS WRONGFUL DEATH BENEFICIARIES OF ERIC CARMICHAEL, DECEASED AND ON BEHALF OF THE ESTATE OF ERIC CARMICHAEL, DECEASED	§	CASE NO. CV2011-163GCD
Plaintiffs,	§	
VS.	§	
WYETH, LLC; SCHWARZ PHARMA, INC.; ALAVEN PHARMACEUTICALS, LLC; GENERICS BIDCO I, LLC D/B/A QUALITEST PHARMACEUTICALS; QUALITEST PHARMACEUTICALS, INC.; and VINTAGE PHARMACEUTICALS, LLC	§	
Defendants.	§	

FIRST AMENDED COMPLAINT
JURY TRIAL DEMANDED

Plaintiffs, DIANE TRUDDLE, KAYLYN TRUDDLE, RICKY CARMICHAEL, and RICKY CARMICHAEL, JR., individually and as wrongful death beneficiaries of Eric Carmichael, Deceased, and on behalf of the Estate of decedent Eric Carmichael, file this Complaint against Wyeth LLC, Schwarz Pharma, Inc., Alaven Pharmaceutical, LLC (collectively referred to as "Branded Defendants") and Generics Bidco I, LLC D/B/A Qualitest Pharmaceuticals, Qualitest Pharmaceuticals, Inc. and Vintage Pharmaceuticals, LLC (collectively referred to as " Manufacturing Defendants") for the reasons set forth herein:



PARTIES

Plaintiffs

1. DIANE TRUDDLE, being over the age of twenty-one, whose residence address is 388 N. Street, Coldwater, Mississippi 38618 and is the natural mother of ERIC CARMICHAEL ("Mr. Carmichael" or "Decedent") and the personal representative of his Estate.

2. KAYLYN TRUDDLE, is a minor resident citizen, whose residence address is 388 N. Street, Coldwater, Mississippi 38618 and is the natural sister of Mr. Carmichael.

3. RICKY CARMICHAEL, being over the age of twenty-one, whose residence address is 4216 Oakcrest Avenue, Memphis, Tennessee 38128 and is the natural father of Mr. Carmichael.

4. RICKY CARMICHAEL, JR., whose residence address is 784 Roanoke, Memphis, Tennessee 38106, and is the natural brother of Mr. Carmichael.

Defendants

5. Defendant Wyeth, LLC, d/b/a Wyeth (hereinafter "WYETH") is a Delaware Corporation with its principal place of business located at 5 Giralda Farms, Madison, New Jersey 07940.

6. References in this Complaint to "WYETH" include Wyeth, LLC individually and as successor- in-interest to A.H. Robins, Inc., American Home Products Corporation, and ESI Lederle, Inc.

7. At all times material hereto, WYETH was engaged in the business of testing, developing, manufacturing, labeling, marketing, distributing, promoting, and/or selling, either directly or indirectly, through third parties, as successor-in-interest, or other related entities, Reglan/metoclopramide and/or metoclopramide HCl in the State of Mississippi and in interstate

commerce. WYETH may be served with process through its registered agent, Prentice Hall Corporation Systems, 830 Bear Tavern Road, Trenton, New Jersey 08628.

8. WYETH manufactures and distributes generic metoclopramide through its ownership of ESI Lederle, Inc. (hereinafter "ESI"), a former subsidiary which merged into WYETH.

9. Defendant SCHWARZ PHARMA, INC., (hereinafter "SCHWARZ") is a Delaware corporation with its principal place of business located at 6140 W Executive Dr., Mequon, Wisconsin 53092.

10. Defendant SCHWARZ, one of its predecessors in interest, and/or one of its families of wholly owned divisions was engaged in the business of testing, developing, manufacturing, labeling, marketing, distributing, promoting, and/or selling, either directly or indirectly, through third parties, as successor in interest, or other related entities, Reglan/metoclopramide and/or metoclopramide HCl in the State of Mississippi, and in interstate commerce. SCHWARZ may be served with process through its registered agent, CSC Entity Services, LLC, 2711 Centerville Road, Wilmington, Delaware 19808.

11. Defendant ALAVEN PHARMACEUTICALS, LLC, (hereinafter "ALAVEN") is a Delaware corporation with its principal place of business located at 200 Cobb Parkway North, Suite 428, Marietta, Georgia 30062.

12. Defendant ALAVEN, its predecessors in interest, and/or one of its families of wholly owned divisions was engaged in the business of testing, developing, manufacturing, labeling, marketing, distributing, promoting, and/or selling, either directly or indirectly, through third parties, as successor in interest, or other related entities, Reglan/metoclopramide and/or metoclopramide HCl in the State of Mississippi, and in interstate commerce. ALAVEN may be

served with process through its registered agent, CT Corporation System, 1201 Peachtree Street, NE, Atlanta, Georgia 30361.

13. Plaintiffs are further informed and believe that Defendant GENERICS BIDCO I, LLC D/B/A QUALITEST PHARMACEUTICALS (hereinafter referred to as "GENERICS BIDCO") is an Alabama Corporation with its principal place of business in Huntsville, Alabama. Plaintiffs are further informed and believe that Defendant GENERICS BIDCO, or a related entity whose identity is presently unknown to Plaintiffs, manufactured, distributed or contracted for the manufacture and distribution of a generic form of metoclopramide in the State of Mississippi that was ingested by Decedent. Defendant GENERICS BIDCO may be served with process through its registered agent: Corporation Trust Company, 1209 Orange Street, Wilmington, Delaware 19810.

14. Plaintiffs are further informed and believe that Defendant QUALITEST PHARMACEUTICALS, INC., (hereinafter referred to as "QUALITEST") is a former Alabama Corporation which had its principal place of business in Alabama. Plaintiffs are further informed and believe that Defendant QUALITEST, or a related entity whose identity is presently unknown to Plaintiffs, manufactured, distributed or contracted for the manufacture and distribution of a generic form of metoclopramide in the State of Mississippi that was ingested by Decedent. Defendant QUALITEST may be served with process through William S. Propst, Sr. 301 Meridian Street Suite 101, Huntsville, Alabama 35801.

15. Plaintiffs are further informed and believe that Defendant VINTAGE PHARMACEUTICALS, LLC (hereinafter referred to as "VINTAGE PHARMACEUTICALS") is an Alabama limited liability company with its principal place of business in Alabama. Plaintiffs are further informed and believe that Defendant VINTAGE, or a related

entity whose identity is presently unknown to Plaintiffs, manufactured, distributed or contracted for the manufacture and distribution of a generic form of metoclopramide in the State of Mississippi that was ingested by Decedent. Defendant VINTAGE may be served with process through its registered agent: Corporation Trust Company, 1209 Orange Street, Wilmington, Delaware.

JURISDICTION AND VENUE

16. Jurisdiction and venue are proper in this Court given that Plaintiffs' claims arise solely under the laws of the State of Mississippi; the Defendants conduct or have conducted business activity in Desoto County, Mississippi and the Defendants have distributed products throughout Desoto County. The decedent was prescribed, purchased and consumed the Defendants' products in Desoto County; and the amount in controversy exceeds this Court's minimum jurisdictional requirement and the maximum jurisdictional amount of County Court.

STATEMENT OF FACTS AND ALLEGATIONS COMMON TO ALL COUNTS

17. Plaintiffs bring this action on behalf of the estate of Mr. Carmichael for the purpose of recovering damages for the personal injuries and ultimate death of Mr. Carmichael as a result of being prescribed and ingesting Reglan, metoclopramide and/or metoclopramide HCl (hereinafter referred to as "Reglan/metoclopramide") as well as the damages suffered by his family as a result of his death.

18. Upon information and belief, Branded and Manufacturing Defendants tested, developed, manufactured, labeled, marketed, promoted, sold, and/or distributed the Reglan/metoclopramide which was ingested by Mr. Carmichael in June 2008.

19. On June 9, 2008, Mr. Carmichael, aged 19 years, was admitted to Baptist

Memorial Hospital Desoto in Southaven, Mississippi ("Baptist Memorial" or "the hospital") by internist Sunil Maholtra, M.D., ("Dr. Maholtra") with complaints of chest pain and gastritis.

20. During the aforesaid hospitalization Dr. Malhotra obtained consultation by a gastro-intestinal specialist, which revealed that Mr. Carmichael had a gastric ulcer, gastritis and esophagitis.

21. On or about June 12, 2008, Dr. Maholtra prescribed Reglan/Metoclopramide (Metoclopramide Hydrochloride) for Mr. Carmichael at a dosage of five milligrams every six hours.

22. Dr. Malhotra diagnosed Mr. Carmichael with a Gastric Ulcer, Gastritis, Esophagitis, Questionable Pericarditis, and heart catherization with normal coronaries and discharged him on June 13, 2008.

23. Metoclopramide and/or metoclopramide HCl, is a dopamine antagonist.

24. Upon information and belief, in prescribing the Reglan/metoclopramide to Mr. Carmichael, Dr. Maholtra relied upon information published in the package inserts and/or the Physicians' Desk Reference (hereinafter referred to as "PDR") or otherwise disseminated by the Reference Listed Drug Company (hereinafter referred to as "RLD") and/or the New Drug Application Holder (hereinafter referred to as "NDA Holder").

25. Mr. Carmichael ingested Reglan/Metoclopramide as directed and prescribed.

26. Mr. Carmichael used the pharmaceutical drugs Reglan/metoclopramide without substantial change in the condition of the drugs between the time of design and manufacture of the drugs and the time he used the drugs as directed.

27. Mr. Carmichael was not aware of information different from or contrary to the inaccurate, misleading, materially incomplete, false and/or otherwise inadequate information disseminated in the PDR, RLD, or by the NDA Holders or ANDA Holders.

28. Shortly after ingesting Reglan/Metoclopramide as prescribed, Mr. Carmichael became depressed and agitated and his mental condition rapidly deteriorated.

29. Prior to ingesting Reglan, Mr. Carmichael had never treated with any mental health practitioner nor had he ever exhibited any signs of depression, mental illness or suicidality.

30. After taking Reglan/Metoclopramide Mr. Carmichael became agitated and began to pull out his intravenous lines and had to be restrained by hospital staff from leaving Baptist Hospital.

31. Mr. Carmichael's patient progress notes for June 12, 2008 state that he became "very aggressive and states he's leaving[. A]ssisted pt back to bed but still fighting. Family notified & Security."

32. Mr. Carmichael also began to hallucinate. He called his mother during the evening of June 12, 2008 and stated to her that someone had just tried to rape him.

33. Prior to the June 12, 2008 administration of Reglan Mr. Carmichael's mental status had been alert, oriented, and cooperative.

34. On or about June 12 or June 13, 2008, Mr. Carmichael began to express implicitly suicidal desires, stating that he wished to join his grandfather and, on another occasion, stating he longed to be with a friend – both of whom were deceased.

35. On June 13, 2008 Mr. Carmichael was discharged from the hospital.

36. Upon discharge, Mr. Carmichael continued to take Reglan as directed and was given a prescription to refill the drug.

37. No defendant warned Mr. Carmichael of any potential adverse reactions to the ingestion of Reglan/Metoclopramide.

38. Mr. Carmichael told other relatives as well as friends of his that the medication he was taking made him feel crazy.

39. On June 17, 2008, Mr. Carmichael went to Wal-Mart's pharmacy and filled a prescription order for five milligram tablets of Metoclopramide.

40. Mr. Carmichael began to take Reglan/Metoclopramide as prescribed by Dr. Malhotra and as dispensed by Baptist Hospital.

41. At times, Mr. Carmichael had difficulties sitting down and could not lay idle.

42. Mr. Carmichael told relatives that he was hearing things and hallucinating.

43. On June 19, 2008, Mr. Carmichael secretly obtained a hand-gun and locked himself in a room at his mother's house, stating to his mother he was going to lie down and take a nap.

44. When Mr. Carmichael told his mother he would take a nap, his mother was on the phone trying to call a psychiatrist to seek a referral of Mr. Carmichael to a mental health practitioner.

45. Mr. Carmichael went into his bedroom, moved a bookcase to block the door, and shot himself in the right temple.

46. Mr. Carmichael was immediately transported to North Oak Regional Medical Center where he was found to be without a pulse secondary to a gun-shot wound to the head, he was declared dead at 3:02 pm.

47. An autopsy was performed by Dr. Stephen T. Hayne, Forensic and Anatomic Pathologist at the Mississippi Medical Examiner's office in Brandon, MS, who concluded that Mr. Carmichael died of cranio-cerebral trauma from a gun-shot wound.

48. Investigators of his death found that shortly before the shooting Mr. Carmichael had sent a text message to a friend stating: **"TO ALL OF THOSE WHO (SIC) ERIC CARMICHAEL AND LOVED HIM I JUST WANT THEM TO KNOW THAT HE IS NOW RESTING IN PEACE."**

49. Mr. Carmichael's use of Reglan/metoclopramide, as prescribed, resulted in serious, permanent and disabling central nervous and extrapyramidal motor systems injuries, specifically akathisia which ultimately led to his suicide.

50. Plaintiffs allege that the pharmaceutical warnings regarding akathisia and/or extrapyramidal systems ("EPS") contained in the Reglan/metoclopramide package inserts were defective and inadequate.

51. Mr. Carmichael developed "akathisia," a sense of restlessness with compulsive constant purposeless movement, which is often associated with fear, depression, and suicidality and/or EPS and other injuries after ingesting Reglan/metoclopramide which led to his suicide.

52. Mr. Carmichael's serious and permanent injuries and ultimate suicide, as described above, came about as a foreseeable and proximate result of the Manufacturing Defendants' dissemination of inaccurate, misleading, materially incomplete, false and otherwise inadequate information concerning the potential effects of exposure to and ingestion of Reglan/ metoclopramide to the medical community, Mr. Carmichael, and other foreseeable users of the drug.

53. Mr. Carmichael was never aware that his development of drug-induced akathisia

was related to his use of metoclopramide. In approximately Fall 2009 Plaintiffs first learned that the FDA had issued a "black boxed warning" and taken action against the various manufacturers of Reglan/metoclopramide to curb the common practice of long term use and citing a potential 20% risk of development of tardive dyskinesia (a subtype of EPS) with such use. Prior to this time, Plaintiffs were wholly unaware of any link between Decedent's use of Reglan and the development of akathisia and/or that there was any possibility of any wrongful act of the Defendants that caused or contributed to Decedent's suicide.

54. Plaintiffs contend that the Manufacturing Defendants, individually and collectively, had purposely suppressed the information necessary to make Decedent and/or his physician aware of the dangers and the association between Reglan and akathisia and/or other EPS, thereby preventing the Decedent from ever knowing of a possible cause of action and preventing Plaintiffs from knowing of such action until such information was publicized and emphasized by the FDA on February 26, 2009.

Defendants' Wrongful Conduct

55. Both the Manufacturing and Branded Defendants' failure to warn Decedent's doctors and/or other healthcare providers of information within their knowledge or possession which indicated a higher risk of serious, permanent, and debilitating side effects related to Reglan/metoclopramide, including but not limited to neurological disorders such as akathisia and/or other EPS.

56. Both the Manufacturing and Branded Defendants jointly and severally marketed, manufactured and/or distributed Reglan/metoclopramide and encouraged the use of these drugs, misrepresented the effectiveness of these drugs and concealed the drug's dangerous side effects.

57. Reglan/metoclopramide is indicated as short-term therapy for symptomatic gastroesophageal reflux and acute and recurrent diabetic gastric stasis.

58. Serious side effects caused by ingesting Reglan/metoclopramide include, but are not limited to, central nervous system disorders, depression with suicidal ideation, akathisia, tardive dystonia, visual disturbances, and interference with drug metabolism.

59. Patients who use Reglan/metoclopramide and are not able to effectively metabolize the drug, are at a greater risk of developing these serious and permanent injuries.

60. Akathisia, one of the serious side effects associated with the ingestion of Reglan/metoclopramide causes motor restlessness which may consist of feelings of anxiety, agitation, jitteriness, and insomnia, as well as inability to sit still, pacing or foot tapping.

61. As stated above, akathisia, a sense of restlessness with compulsive constant purposeless movement, is often associated with fear, depression, and suicidality.

62. EPS, some of the serious side effects associated with the ingestion of Reglan/metoclopramide, are various movement disorders suffered as a result of taking dopamine antagonists.

63. Mr. Carmichael's akathisia and/or EPS, which was caused by the ingestion of metoclopramide, led to his suicide.

64. On or around December 27, 2001, Defendant SCHWARZ purchased from Defendant WYETH the rights and *liabilities* associated with Reglan/metoclopramide, the terms of which, upon information and belief, obligated SCHWARZ to be responsible for claims related to the ingestion or use of Reglan/metoclopramide.

65. Defendant SCHWARZ entered into an indemnification agreement with Defendant WYETH over the purchase of the innovator, WYETH's, Reglan®, which included disclosure of clinical studies on Reglan/metoclopramide that were not publicly available.[1]

66. Because Defendant SCHWARZ acquired Defendant WYETH's Reglan/metoclopramide assets and liabilities while WYETH was involved in on-going litigation regarding Reglan/metoclopramide, and nevertheless agreed to indemnify WYETH against all claims related to the ingestion of the drug, SCHWARZ knew or should have known that the label for Reglan/metoclopramide misrepresented the safety of the drug, withheld information regarding the frequency of side effects of the drug, and knew or should have known of the safety issues surrounding it.

67. In or around February of 2008, Defendant ALAVEN purchased from Defendant SCHWARZ the rights and *liabilities* associated with Reglan/metoclopramide, the terms of which, upon information and belief, obligated ALAVEN to be responsible for claims related to the ingestion or use of Reglan/metoclopramide.

68. Defendant ALAVEN entered into an indemnification agreement with Defendant SCHWARZ over the purchase of the innovator, WYETH's, Reglan®, which included disclosure of clinical studies on Reglan/metoclopramide that were not publicly available.[2]

69. Because Defendant ALAVEN acquired Defendant SCHWARZ's Reglan/metoclopramide assets and liabilities while SCHWARZ was involved in on-going litigation regarding Reglan/metoclopramide, and nevertheless agreed to indemnify SCHWARZ against all claims related to the ingestion of the drug, ALAVEN knew or should have known that

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[1] Plaintiffs do not have information regarding the maximum amount of liability under the defendants' indemnification agreement.

[2] Plaintiffs do not have information regarding the maximum amount of liability under the defendants' indemnification agreement.

the label for Reglan/metoclopramide misrepresented the safety of the drug, withheld warnings of the known side effects of the drug, and knew or should have known of the safety issues surrounding it.

70. Under the FDA schema, the Branded Defendants were designated as the Reference Listed Drug ("RLD") and/or New Drug Application ("NDA") Holder for Reglan/metoclopramide during time periods relevant to this case.

71. At all times material hereto, the Branded Defendants as NDA Holders and/or RLD companies, were aware of the serious side effects caused by Reglan/metoclopramide including, but not limited to, central nervous system disorders, depression with suicidal ideation, akathisia, tardive dyskinesia, tardive dystonia, visual disturbances and interference with drug metabolism.

72. At all times material hereto, the Branded Defendants as the NDA Holders and/or RLD companies, were aware of the serious side effects caused by Reglan/metoclopramide including, but not limited to, central nervous system disorders, EPS, depression with suicidal ideation, akathisia, tardive dyskinesia, tardive dystonia, visual disturbances and interference with drug metabolism.

73. The Branded and Manufacturing Defendants have a duty to provide accurate and adequate warnings to the medical community, conduct safety surveillance of adverse events for their drugs, and to report *any* data related to the safety and/or accuracy of the warnings and information disseminated regarding the drug.

74. The Branded Defendants represented that Reglan/metoclopramide was safe for use to treat gastritis/gastroesophageal reflux knowing that the drug was not safe for that purpose and was dangerous to the health and body of Decedent.

75. The Branded Defendants represented that Reglan/metoclopramide caused minimal side effects knowing that the drug caused brain injury, central nervous system side effects, and EPS including akathisia and suicidality among other side effects, far more frequently than represented.

76. The Branded Defendants had actual knowledge, through their own studies and studies by independent investigators, that doctors frequently prescribed Reglan/metoclopramide which was unsafe for patients and could lead to depression and suicidality.

77. The Branded Defendants also had actual knowledge, through research by independent investigators, of the risk of developing drug-induced akathisia leading to suicide.

78. The Branded Defendants knew, or through the exercise of reasonable care should have known, that many patients who use Reglan/metoclopramide are not able to effectively metabolize it and that, as a foreseeable consequence of their inability to effectively metabolize the drug, those patients have a greater risk of developing serious and permanent injuries.

79. The Branded Defendants had actual knowledge of facts which demonstrated that representations in the Reglan/metoclopramide package insert, the PDR, and literature they distributed to physicians were false and misleading.

80. The Branded Defendants failed to correct their monograph and/or disclose that knowledge to the medical community, Decedent, and other foreseeable users.

81. It is the public policy of the United States and of this state, as reflected in the Hatch-Waxman Act, to encourage the availability of cheaper, generic drug products that are therapeutically equivalent to name brand products and to encourage the substitution, as appropriate, of such generic products for name brand products in patients' medical therapy.

82. The Branded Defendants as a prescription drug manufacturer and/or distributor, knew or should have realized that so-called "drug product selection laws," enacted in every state, including this state, authorize or require a prescription for a drug identified by product brand name or by generic name to be filled, subject to certain limitations, with a generic drug product that is therapeutically equivalent to the name brand drug product.

83. The Branded Defendants knew or ought to have realized that generic drug manufacturers customarily copy verbatim the package insert for the name brand prescription drug product.

84. The Branded Defendants knew or ought to have known that the generic drug manufacturers also typically rely upon the marketing efforts of the name brand manufacturer to generate sales of their own products.

85. The Branded Defendants knew or ought to have realized that physicians commonly consult the information disseminated by the name brand manufacturer, in the PDR or otherwise, and rely upon that information in their decisions concerning the prescribing of those products for their patients.

86. The Branded Defendants knew or should have known, specifically, that physicians would rely upon the information disseminated to them by the name brand manufacturer, regardless of whether the prescriptions might be filled with either the name brand product, Reglan, or generic metoclopramide, and that many patients, in accordance with those prescriptions, would be likely to ingest generic metoclopramide.

87. Qualitest, a Defendant involved in the manufacture and distribution of generic metoclopramide and metoclopramide HCl, submitted an Abbreviated New Drug Application

(ANDA) to the FDA, based on representations made by the RLD companies, requesting permission to manufacture, market, and distribute generic Reglan/metoclopramide.

88. Under the ANDA process, the Code of Federal Regulations *required* a company involved in the manufacture and distribution of generic metoclopramide and metoclopramide HCI to submit labels for Reglan/metoclopramide initially identical in all material aspects to the reference listed drug label.

89. Under the Code of Federal Regulations, a company involved in the manufacture and distribution of generic metoclopramide and metoclopramide HCI has a duty to ensure their Reglan/metoclopramide warnings to the medical community were accurate and adequate, to conduct post-marketing safety surveillance, to review all adverse drug event information, and to report any information bearing on the risk and/or prevalence of side effects caused by Reglan/metoclopramide.

90. Under the Code of Federal Regulations, if a defendant involved in the manufacture and distribution of generic metoclopramide and metoclopramide HCI discovers information in the course of the fulfillment of their duties as outlined above, they must report that information to the medical community, Decedent, and other foreseeable users of Reglan/metoclopramide to ensure that their warnings are continually accurate and adequate.

91. The Manufacturing Defendants failed to investigate the accuracy of their metoclopramide and/or metoclopramide HCl drug labels.

92. The Manufacturing Defendants failed to review the medical literature for the metoclopramide and/or metoclopramide HCl.

93. The Manufacturing Defendants relied upon the name brand manufacturer and the referenced listed drug companies to review the aforementioned medical literature for Reglan/metoclopramide.

94. Under the FDA schema, if the FDA approves a label change as requested by a NDA holder (also referred to as the RLD company), the ANDA holder must also amend its label.

95. The Manufacturing Defendants failed to communicate the frequency of severe neurological side effects resulting from the ingestion of drugs containing Reglan/metoclopramide.

96. Both Branded and Manufacturing Defendants to this action who have manufactured, marketed and distributed generic Reglan/metoclopramide have failed to provide accurate and adequate warnings to the medical community, Decedent, and other foreseeable users of Reglan/metoclopramide regarding the frequency of side effects with its use.

97. Both the Branded and Manufacturing Defendants disseminated to physicians, through package inserts, the publication of the PDR, and otherwise, information concerning the properties and effects of Reglan/metoclopramide, with the intention that physicians would rely upon that information in their decisions concerning the prescription of Reglan/metoclopramide to their patients.

98. The Branded and Manufacturing Defendants knew, or should have known through the exercise of reasonable care, that the package insert for Reglan/metoclopramide substantially understated the frequency of side effects with ingesting the drug.

99. The Branded and Manufacturing Defendants failed to use reasonable care to adequately warn physicians about the true frequency of both short-term and long-term use, even

after several injured patients filed lawsuits alleging inadequate warnings and produced competent expert testimony supporting their allegations.

100. The Branded and Manufacturing Defendants owed a duty in all of their several undertakings, including the dissemination of information concerning Reglan/metoclopramide, to exercise reasonable care to ensure that they did not create unreasonable risks of personal injury to others.

101. Reglan/metoclopramide was widely promoted by the Branded and Manufacturing Defendants as a safe and effective treatment of diabetic gastroparesis, gastroesophageal reflux disease (GERD) and other gastrointestinal disorders.

102. The Branded and Manufacturing Defendants failed to adequately conduct and report post market safety surveillance on Reglan/metoclopramide.

103. The Branded and Manufacturing Defendants failed to review all adverse drug event information and to report information bearing upon the adequacy and accuracy of their warnings, efficacy, or safety, including the frequency of side effects caused by Reglan/metoclopramide.

104. The Branded and Manufacturing Defendants failed to monitor all relevant scientific literature related to Reglan/metoclopramide.

105. The Branded and Manufacturing Defendants failed to disclose material safety information regarding the serious and permanent side effects caused by taking Reglan/metoclopramide.

106. The Branded and Manufacturing Defendants failed to report data, *regardless of the degree of significance,* regarding the adequacy and/or accuracy of their warnings, efficacy or safety of Reglan/ metoclopramide.

107. The Branded and Manufacturing Defendants concealed the fact that Reglan/metoclopramide is a neuroleptic agent and dopamine antagonist, which can be expected to lead to akathisia, tardive dyskinesia and other extrapyramidal side effects with approximately the same high frequency, as other neuroleptic drugs and that epidemiological studies have consistently confirmed this expectation.

108. Some or all Defendants, as a result of their participation as Defendants in previous litigation concerning Reglan/metoclopramide products received clear notice of WYETH's suppression of important safety information concerning Reglan/metoclopramide yet, despite this notice, chose to ignore the information and join consciously in the suppression.

COUNT I -- NEGLIGENCE

109. Plaintiffs reallege and incorporate by reference the preceding paragraphs above, as if set forth in full hereinafter.

110. The Branded and Manufacturing Defendants owed a duty to the general public and specifically to Decedent to exercise reasonable care in the design, study, development, manufacture, promotion, sale, marketing and distribution of their prescription medications, including the Reglan/ metoclopramide at issue in this lawsuit.

111. The Branded and Manufacturing Defendants further failed to exercise reasonable care in the design of Reglan/metoclopramide because as designed, it was capable of causing serious personal injuries which could lead to suicide/death such as those suffered by Mr. Carmichael during foreseeable use.

112. The Branded and Manufacturing Defendants also failed to exercise reasonable care in the marketing of Reglan/metoclopramide because they failed to warn that, as designed,

Reglan/metoclopramide was capable of causing serious personal injuries which could lead to suicide/death such as those suffered by Mr. Carmichael during foreseeable use.

113. The Branded and Manufacturing Defendants breached their duty and were negligent in their actions, misrepresentations, and omissions toward Decedent in that Defendants:

a. Failed to use due care in developing, testing, designing and manufacturing Reglan/metoclopramide so as to avoid the aforementioned risks to individuals when Reglan/metoclopramide was being used for treatment of patients;

b. Failed to accompany their product with proper or adequate warnings regarding adverse side effects and health risks associated with the use of Reglan/metoclopramide and the comparative severity and duration of such adverse effects;

c. Failed to accompany their product with proper or adequate rate of incidence or prevalence of permanent irreversible neurological damage;

d. Failed to provide warnings that accurately reflected the symptoms, scope or severity of the side effects and health risks;

e. Failed to provide warnings that adequately reflected the possible development of akathisia which leads to fear, depression and suicidality and/or the risk of suicide;

e. Failed to conduct adequate pre-clinical and clinical testing and post-marketing surveillance to determine the safety of Reglan/metoclopramide;

f. Failed to provide adequate training or information to medical care providers for appropriate use of Reglan/metoclopramide;

g. Failed to adequately warn consumers and medical prescribers (but instead actively encouraged the sale of Reglan/metoclopramide), about the following: (1) that Reglan/metoclopramide should not be prescribed for more than twelve weeks; (2) that Reglan/metoclopramide can cause neuromuscular side effects, including, but not limited to, akathisia and tardive dyskinesia; (3) that Reglan/metoclopramide should be discontinued in the face of involuntary facial, tongue, jaw, limb or trunk movements or motor restlessness consisting of feelings of anxiety, agitation, jitteriness, and insomnia, as well as inability to sit still, pacing or foot tapping; and (4) that the health risks posed by Reglan/metoclopramide may become debilitating, difficult, and painful, necessitating lengthy and/or repeated visits to the doctor, clinic, or hospital and (5) that there was a potential risk of suicide;

h. Failed to adequately test and/or warn about the use of Reglan/metoclopramide, including, without limitation, the possible adverse side effects and health risks caused by the use of Reglan/metoclopramide;

i. Failed to adequately warn users, consumers and physicians about the severity, scope and likelihood of neurological damage and related dangerous conditions to individuals taking Reglan/metoclopramide including the risk of suicide; and

j. Representing to physicians, including but not limited to Decedent's prescribing physician, that this drug was safe and effective for use.

114. The Reglan/metoclopramide was in substantially the same condition when it was ingested by Decedent as it was in when it left the control of the Manufacturing Defendants. Reglan/metoclopramide's capability to cause serious personal injuries and damages such as those suffered by Decedent was not due to any voluntary action or contributory negligence of Decedent. The Reglan/metoclopramide was consumed by Decedent as directed and without change in its form or substance.

115. The Branded and Manufacturing Defendants' failure to exercise reasonable care in the design and/or marketing of Reglan/metoclopramide was a proximate cause of Decedent's injuries, damages and ultimate suicide. Plaintiffs seek all damages to which Decedent may have been justly entitled.

COUNT II – STRICT LIABILITY

116. Plaintiffs reallege and incorporate by reference the preceding paragraphs above, as if set forth in full hereinafter.

117. Plaintiffs claim that Manufacturing Defendants are liable under the theory of strict products liability. Defendants were at all times relevant to this suit, and now are, engaged in the business of designing, manufacturing, testing, marketing, and placing into the stream of commerce pharmaceuticals for sale to, and use by, members of the public, including the

Reglan/metoclopramide at issue in this lawsuit. The Reglan/metoclopramide manufactured by Manufacturing Defendants reached the Decedent without substantial change and was ingested as directed. The Reglan/metoclopramide was defective and unreasonably dangerous when it entered into the stream of commerce and when used by the Decedent.

118. Reglan/metoclopramide was unreasonably defective in design and marketing, considering the utility of the product and the risk involved in its use, because as designed and marketed, Reglan/metoclopramide could cause injuries such as those suffered by the Decedent during foreseeable use. This fact was known to Manufacturing Defendants at the time Reglan/metoclopramide was placed into the stream of commerce, but was not readily recognizable to an ordinary consumer, including the Decedent. Nonetheless, Manufacturing Defendants failed to warn that Reglan/metoclopramide as designed and marketed was capable of causing serious personal injuries such as those suffered by the Decedent during foreseeable use. Such a failure to warn rendered the Reglan/metoclopramide unreasonably dangerously defective as designed and marketed.

119. The defective and unreasonably dangerous design and marketing of Reglan/metoclopramide was a direct, proximate and producing cause of the Decedent's injuries, death and damages. Under strict products liability theories set forth in Restatement (Second) of Torts, Manufacturing Defendants are liable to Plaintiffs for all damages claimed in this case, including punitive damages.

COUNT III -- BREACH OF WARRANTIES

120. Plaintiffs reallege and incorporate by reference the preceding paragraphs above, as if set forth in full hereinafter.

121. Branded and Manufacturing Defendants were at the time of the acts forming the basis of this lawsuit, and now are, merchants with respect to the Reglan/metoclopramide at issue in this lawsuit. Branded and Manufacturing Defendants marketed and promoted their Reglan/metoclopramide as safe and efficacious for its intended uses. The Reglan/metoclopramide consumed by Decedent reached him without substantial change in its condition and was used by Decedent as intended by defendants. Branded and Manufacturing Defendants expressly and impliedly warranted that the Reglan/ metoclopramide were not unreasonably dangerous and instead were merchantable and fit for its intended use by Decedent.

122. Branded and Manufacturing Defendants breached these warranties (both express and implied) as the Reglan/metoclopramide was not merchantable, was unfit for its intended use and was unreasonably dangerous when comparing the benefits to the risks associated with its use. Mr. Carmichael was injured and committed suicide as a result of these breaches of warranties.

COUNT IV– MISREPRESENTATION AND FRAUD

123. Plaintiffs hereby incorporate by reference all of the above allegations as if fully set forth herein.

124. Manufacturing Defendants through their advertising, labeling, marketing, and sales/detail persons, made significant representations, which were false, knowing that such representations were false and/or with reckless disregard for the truth or falsity of such representations, with the intent that Decedent rely on such material representations and in doing so violated the Mississippi Consumer Protection Act, 75:24-5 *et seq*; Decedent acted in actual and justifiable reliance on such material misrepresentations and was injured as a result.

125. In addition, and in the alternative if necessary, Manufacturing Defendants knowingly omitted and downplayed material information, which omission constitutes a positive misrepresentation of material fact, with the intent that Decedent rely on defendants' misrepresentations; Decedent acted in actual and justifiable reliance on manufacturing defendants' representations and was injured as a result.

126. Manufacturing Defendants committed constructive fraud by breaching one or more legal or equitable duties owed to Decedent relating to the Reglan/metoclopramide at issue in this lawsuit, said breach or breaches constituting fraud because of their propensity to deceive others or constitute an injury to public interests or public policy.

127. Manufacturing Defendants misrepresented to the FDA, Decedent, and the health care industry the safety and effectiveness of Reglan/metoclopramide and/or fraudulently, intentionally and/or negligently concealed material information, including adverse information regarding the safety and effectiveness of Reglan/metoclopramide.

128. Manufacturing Defendants made these misrepresentations and actively concealed adverse information at a time when they knew, or should have known, that Reglan/metoclopramide had defects, dangers, and characteristics that were other than what they had represented to Decedent and the health care industry generally. Specifically, manufacturing defendants misrepresented to and/or actively concealed from Decedent and the consuming public that:

a. Reglan/metoclopramide had statistically significant increases in neuromuscular side effects which could result in serious injury;

b. Patients on Reglan/metoclopramide should not take it more than twelve weeks;

c. Reglan/metoclopramide was not fully and adequately tested for the neuromuscular side effects.

129. As a direct and proximate result of the fraudulent acts and omissions, suppression and misrepresentation of defendants, Decedent suffered significant and ongoing injuries and damages. Further, because manufacturing defendants' conduct was willful, reckless, intentional and maliciously fraudulent, Plaintiffs are entitled to an award of exemplary damages.

COUNT V—MISREPRESENTATION AND FRAUD
(As to Branded Defendants)

130. Plaintiffs hereby incorporate by reference all of the above allegations as if fully set forth herein.

131. As innovator of the drug Reglan, given their vast experience as drug product manufacturers, the Branded Defendants were aware their drug product would be the forerunner to generics metoclopramide and metoclopramide HCl.

132. Given the foreseeable advent of generic versions of the drug they created, defendants the Branded Defendants had a duty to all foreseeable consumers of the research conducted (whether data was released or not), labeling language, the monograph submitted to the Physician's Desk Reference, and data submitted to the FDA. Foreseeable consumers of this material would clearly include prescribing physicians and persons who would be dispensed and subsequently ingest metoclopramide and metoclopramide HCl.

133. Thus, the Branded Defendants had a clear duty to dispensers and consumers of generic forms of Reglan to warn of foreseeable risk and harm.

134. The Branded Defendants through their advertising, labeling, marketing, and sales/detail persons, made significant representations, which were false, knowing that such representations were false and/or with reckless disregard for the truth or falsity of such representations, with the intent that Decedent rely on such material representations and in doing

so violated the Mississippi Consumer Protection Act, 75:24-5 *et seq*; Decedent acted in actual and justifiable reliance on such material misrepresentations and was injured as a result.

135. In addition, and in the alternative if necessary, the Branded Defendants knowingly omitted and downplayed material information, which omission constitutes a positive misrepresentation of material fact, with the intent that Decedent rely on the branded defendants' misrepresentations; Decedent acted in actual and justifiable reliance on the branded defendants' representations and was injured as a result.

136. The Branded Defendants committed constructive fraud by breaching one or more legal or equitable duties owed to Decedent relating to the Reglan/metoclopramide at issue in this lawsuit, said breach or breaches constituting fraud because of their propensity to deceive others or constitute an injury to public interests or public policy.

137. The Branded Defendants misrepresented to the FDA, Decedent, and the health care industry the safety and effectiveness of Reglan/metoclopramide and/or fraudulently, intentionally and/or negligently concealed material information, including adverse information regarding the safety and effectiveness of Reglan/metoclopramide.

138. The Branded Defendants made these misrepresentations and actively concealed adverse information at a time when they knew, or should have known, that Reglan/metoclopramide had defects, dangers, and characteristics that were other than what they had represented to Decedent and the health care industry generally. Specifically, Branded Defendants misrepresented to and/or actively concealed from Decedent and the consuming public that:

a. Reglan/metoclopramide had statistically significant increases in neuromuscular side effects which could result in serious injury;

b. Patients on Reglan/metoclopramide should not take it more than twelve weeks;

c. Reglan/metoclopramide was not fully and adequately tested for the neuromuscular side effects.

139. As a direct and proximate result of the fraudulent acts and omissions, suppression and misrepresentation of the Branded Defendants, Decedent suffered significant injuries, damages, and ultimately committed suicide. Further, because branded defendants' conduct was willful, reckless, intentional and maliciously fraudulent, Plaintiffs are entitled to an award of exemplary damages.

COUNT VI -- NEGLIGENCE PER SE

140. Plaintiffs hereby incorporate by reference all of the above allegations as if fully set forth herein.

141. The product label and package insert for Reglan/metoclopramide is misbranded within the meaning of 21 U.S.C. § 352(a) and (f) because it was false and misleading and failed to give adequate warnings and directions for use by physicians who prescribe Reglan/metoclopramide. Because the Branded and Manufacturing Defendants each had a statutory duty under 21 U.S.C. § 352(a) and (f) not to misbrand Reglan/metoclopramide and because each of them violated this duty, they were guilty of negligence per se. In addition, and more particularly, because the Branded and Manufacturing Defendants knew, or should have known, that physicians commonly prescribed Reglan/metoclopramide for long-term use, beyond the 12 week intended use that was approved by the FDA, pursuant to 21 CFR 201.128, long-term use became an "intended use" which required the defendants, and each of them, to provide adequate labeling for such a drug which accords with such other uses to which the article was commonly prescribed. Their failure to adequately warn about the frequency of side effects associated with use constitutes negligence per se. This negligence per se proximately caused injury and ultimate death to Mr. Carmichael as described more fully herein.

DAMAGES

142. Plaintiffs reallege and incorporate by reference the preceding paragraphs above, as if set forth in full hereinafter.

143. As a result of the Branded and Manufacturing Defendants' negligence or gross negligence, misrepresentations, and other conduct as set forth herein, Decedent, his estate, and others sustained injuries and incurred substantial damages including, but not limited to, the following:

(a) Medical expenses;

(b) Severe pain of body and mind;

(c) Loss of earning capacity;

(d) Loss of enjoyment of life;

(e) Loss of consortium;

(f) Loss of love, society and companionship;

(g) Death;

(h) Incurred medical expenses;

(i) Funeral costs and burial costs; and

(f) Such other damages which the Court or jury deem just or appropriate to award under the circumstances.

PUNITIVE DAMAGES AGAINST ALL DEFENDANTS

144. The actions of all Defendants were in reckless disregard of the rights of the decedent, thus authorizing his estate to collect as punitive damages a further sum as to be determined.

WHEREFORE PREMISES CONSIDERED, Plaintiffs respectfully demand a trial by jury and respectfully request that judgment be entered against the Defendants Wyeth LLC,

Schwarz Pharma, Inc., Alaven Pharmaceutical, LLC and Generics Bidco I, LLC D/B/A Qualitest Pharmaceuticals, Qualitest Pharmaceuticals, Inc. and Vintage Pharmaceuticals, LLC individually, jointly and severally, for compensatory damages and punitive damages as shown by the evidence, and pre-judgment and post-judgment interest, all costs and all other relief of any kind deemed proper in the premises.

JURY DEMANDED

Respectfully submitted this the 17 day of August, 2011.

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